



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR 5 2000

0324 '00 APR -6 P1:25 21

. The Honorable Olympia J. Snowe
House of Representatives
Washington, D.C. 20510-1903

Dear Ms. Snowe:

Thank you for your letter of January 28, 2000, on behalf of your constituent, Ms. Debra M. Seeley of Winslow, Maine. Ms. Seeley has a condition, celiac sprue, which causes intolerance to the protein component of the gluten in wheat, barley, rye, and oats. This means she needs to avoid food products containing these grains. She is concerned that food manufacturers are including these grains in their products without stating so on the label's ingredient statement. She would like legislation to require the disclosure of all ingredients on food labels.

By way of background, the Federal Food, Drug, and Cosmetic (FD&C) Act requires that all foods fabricated from two or more ingredients must declare each ingredient by its common or usual name in the ingredient statement in descending order of predominance by weight. The FD&C Act provides two narrow exemptions from ingredient labeling requirements. The first one provides that spices, flavorings, and certain colorings may be declared collectively without naming each one. The second one provides that incidental additives, such as processing aids that are present at insignificant levels and do not have a functional effect in the finished food, do not have to be declared on the label.

Staff at the Food and Drug Administration's (FDA or the Agency) Center for Food Safety and Applied Nutrition (CFSAN) have been considering whether to revise the regulation regarding natural flavorings to make it more meaningful to consumers. We have forwarded your correspondence to our staff at CFSAN for their consideration.

In addition, we have recently received a citizen petition raising concerns similar to those raised by Ms. Seeley and

99P-2148

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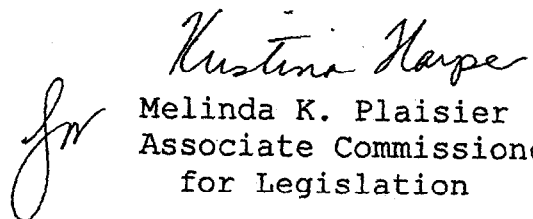
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requesting FDA to amend its food labeling regulations to require the provision of source information for modified food starch, spices, natural and artificial flavorings, and other non-specific ingredients. We have forwarded your correspondence to the docket for this matter for inclusion in the record. Please be assured that we will consider all comments before making a final decision on this issue.

FDA understands the difficulties faced by persons with food allergies and food intolerance. Being able to identify and avoid allergens and other specific ingredients is of great importance to such people. We have enclosed a Notice to Manufacturers that FDA distributed to food manufacturers, trade associations, and other food industry groups. It advises the industry on the steps that it needs to take to ensure that allergens are declared on food labels. FDA encourages manufacturers to specifically declare ingredients used as flavors and colors that are known allergens. Please note that wheat is included in the list of common allergens. While the Agency recognizes that celiac sprue is a food intolerance and not an allergy, we believe that the inclusion of wheat in the list will help enable persons with celiac sprue to avoid certain proscribed products.

We trust this information responds to your concerns. If we may be of any further assistance, please contact us again.

Sincerely,


Melinda K. Plaisier
Associate Commissioner
for Legislation

Enclosure

cc: Dockets Management Branch
(Docket No. 99P-2148/CP)

OLYMPIA J. SNOWE
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United States Senate
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January 28, 2000

Melinda K. Plaiser
Associate Commissioner For Legislative Affairs
Food and Drug Administration
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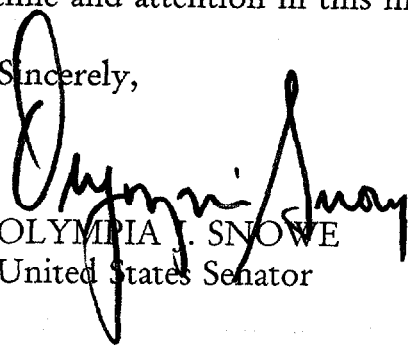
Dear Ms. Plaiser:

I am contacting you on behalf of my constituent, Debra Seeley of Winslow Maine.

Ms. Seeley has expressed concern about the labeling of products containing gluten. She is concerned that insufficient labeling may pose a threat to people like herself. I have enclosed a copy of her correspondence for your review. Any assistance you could provide in addressing these concerns would be greatly appreciated.

Thank you in advance for your time and attention in this matter.

Sincerely,


OLYMPIA J. SNOWE
United States Senator

OJS:dmr

00-856

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Author: "Seeley; Debra" <dseeley@sfacpa.com> at Internet
Date: 12/3/1999 10:50 AM
Normal
TO: olympia at Snowe-DC
Subject: Food Labeling

DMA
DEC

531137

----- Message Contents

Dear Senator Snowe:

I have celiac disease. It is a small intestinal disease whereby celiacs cannot consume wheat, rye, oats, barley, and derivatives of these grains. Consumption of these grains can make a person very sick and can be deadly if gluten (the protein in grains, which is poison to our bodies) is ingested. The gluten damages the small intestine so food cannot be digested and absorbed into the system. It is very difficult to find the hidden gluten when manufacturers list things like modified food starch, vinegar, and natural flavors in there ingredients list. Celiacs need to know the source of these things to determine if we can consume the product or not. Some celiacs have bad reactions even to small traces of these grains. Please help us in changing the food labeling laws to include the specific ingredients in products. If specifics are on the labels, our meal plans may not have to be so restricted. It would also be a big plus if the words "gluten free" were on the label. There are about 3000 members (world wide) of an e-mail listserv for celiacs. I realize that this is a small number. It does not include many people who are undiagnosed and those who do not have e-mail access. We should not be treated as a minority. We deserve the same quality of life as a non-celiac.

The second item I would like to make you aware of is that there are many doctors in the US that do not know ANYTHING about celiac disease (my general doctor included). My doctor says I will have to educate him. Should the patient be responsible for this? Doctors somehow need to be educated about this disease. Many people are misdiagnosed because the symptoms for celiac (vomiting, diarrhea, stomach pain, weight loss, etc.) are the same as the symptoms of many other things.

The third and final item is financial support for celiac research. They have come a long way, but still have a long way to go to find a cure or a way to prevent celiac disease. Donations/grants can be sent to:

The Center for Celiac Research
Pam King
Director of External Affairs
University of Maryland School of Medicine
700 West Lombard Street
Baltimore MD 21201

Thank you for your consideration of these requests.

Sincerely,

Debbie Seeley

Mailing address:

Debra M. Seeley
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South Pond Road
Winslow, ME 04901